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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,159	10/12/2000	Peter H. St. Georges-Hyslop	1034/1F808-US7	2656

7590 10/21/2003  
Paul F Fehlner PhD  
Darby & Darby PC  
805 Third Avenue  
New York, NY 10022

EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/689,159

Applicant(s)

ST. GEORGES-HYSLOP ET AL.

Examiner

Sharon L. Turner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 74-81 is/are pending in the application.
- 4a) Of the above claim(s) 80 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 74-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 74-81 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **Response to Amendment**

1. The amendment and drawings filed 8-6-03 have been entered into the record and have been fully considered.
2. Claims 1-73 are cancelled. Amended claims 74-81 are pending.
3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

### **Rejections Maintained**

#### **Election/Restriction**

5. Applicant's election without traverse of Group I, claims 73-79 to the extent of SEQ ID NO:2, and epitope 346-360 of SEQ ID NO:2 in Paper No. 12 is acknowledged.
6. Claims 80-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

Applicants have chosen to traverse their previous election **without** traverse in paper No. 12, on the basis that the sequences share significant similarity. Applicant's traversal is not timely. Moreover it is noted that the sequences differ in structure and requisite function. A search for any one element is not co-extensive with any other and search and examination of the multiple sequences in a single application bears undue burden upon the Examiner.

### **Claim Objections**

7. Claims 74-79 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

“Since the decisions in *In re Weber* \*\*, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish* , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi* , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.”

In the instant case claims 74-79 recite the different amino acid sequences of SEQ ID NO's 4, 134, 136 and 138 and fragments of SEQ ID NO:2 that lack common structure and unity of invention. A search of SEQ ID NO:2 would not reveal relevant art to the uncommon sequences.

#### **Claim Rejections - 35 USC § 112**

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 74-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the term “specifically binds” and/or “selectively recognizes”. Yet the artisan cannot discern the extent or breadth of protection sought absent clarification of the metes and bounds of the term from the specification. For example, it is unclear the extent to which cross reactivity or specificity

is encompassed amongst the antibodies and peptides. Clarification is required.

Applicants argue that as amended the claims are drawn to antibodies "specific for" as supported at p. 7, lines 1-13. Applicants additionally argue that antibody specificity is a well-established concept of the art. Applicants submit that the amendment obviates the rejection.

Applicant's arguments filed 8-6-03 have been fully considered but are not persuasive. Neither the amendment nor the specification clarifies applicant's intention with respect to the metes and bounds of antibody specificity and/or cross-reactivity. The specification at p. 7 notes antibodies specific to particular epitopes or peptides of at least six amino acid residues. Thus, applicant's referral to the specification establishes the art recognized principle that antibodies may be specific for short epitopic sequences while cross reacting with alternative sequences to the full length protein. Applicant's claim structure suggests (i.e., by dependency) that such cross-reactivity is not applicant's intention as to the metes and bounds of the claims. However, applicant's amendment and arguments fail to clarify this issue. There is no guidance as to whether or not antibodies to cross-reactive epitopes are intended to be encompassed by the recitations. The Examiner notes that while antibody specificity is well recognized in the art, applicant's recitation fails to establish clarity as to whether the recitation is intended to include or exclude cross-reactive epitopes and sequences. If it is applicant's intention to include cross-reactive epitopes, then applicant's claim structure is improperly dependent and new art may apply. If it is applicant's intention to exclude cross reactive epitopes then applicant should state so on the record, i.e., that all

antibodies encompassed by the claims should exhibit binding specific for SEQ ID NO:2 and not to alternative sequences.

### **Status of Claims**

10. No claims are allowed.
11. Applicant's request for rejoinder has been fully considered but is not persuasive as to applicant's claims which are not deemed allowable and subject to rejoinder at this time. Moreover, it is noted that the claims are not commensurate in scope to the elected invention.

### **Conclusion**

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

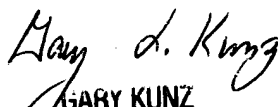
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13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
October 14, 2003

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600